Options for Reporting Biomedical Equipment That Is Y2K Compliant

You may use one of three options to report medical devices and/or scientific research equipment that are Y2K compliant to the Clearinghouse. Please review the options below, and determine which option is best suited for reporting your company's compliant product information.

OPTION #1 – Paper Reporting

1. Use the enclosed, pre-filled **Additional Information Request Form – Manufacturer Reporting Y2K Compliant Products – FORM FDA 3473** to verify and correct, or provide any missing information about your company and the Y2K Contact person.

2. Use the enclosed **Compliant Products – FORM FDA 3474** to report all medical devices and/or scientific research equipment that are Y2K compliant.
   - Duplicate the form as necessary.

3. Use one of the following methods to return the completed forms:
   Mail – Year 2000 Coordinator (HFZ-Y2K)
   Center for Devices and Radiological Health, FDA
   9200 Corporate Boulevard
   Rockville, Maryland 20850
   USA
   FAX – 1-301-881-1848

OPTION #2 – Report Online at FDA's Web Site

1. Beginning **APRIL 5, 1999**, you can report online at FDA's Web site, medical devices and/or scientific research equipment that are Y2K compliant.

2. Go to the following URL address – http://www.fda.gov/cdrh/yr2000/y2kform.html or;

   Go to the FDA Web site (http://www.fda.gov), select Year 2000, and then select the following links:
   Information For Industry
   Forms For Electronic Submission and Update of Year 2000 Data By Manufacturers
   Access The Forms For Submitting Information

3. On the login screen enter:
   Login ID –
   Password –

4. Follow the instructions on each screen for completing the online forms for manufacturer, contact, and product specific information.
   - For screen specific help, click the **Assist Me!** button.

OPTION #3 – Electronic File Submission of Y2K Compliant Products (E-File)

1. To use E-File, you will need to report using **Microsoft Excel 97** or **Microsoft Excel 5.0/95**.

2. Go to the following URL address – http://www.fda.gov/cdrh/yr2000/efile/reporting.html or;

   Go to the FDA Web site (http://www.fda.gov), select Year 2000, and then select the following links:
   Information For Industry
   Forms For Electronic Submission and Update of Year 2000 Data By Manufacturers
   E-File Y2K Compliant Products

3. Click on the option to download the E-File reporting template – **Y2KEFILE.XLS**.

4. Click on the option to view, download, or print the **E-File Reporting Format Instructions**. For your convenience, these are available in three formats:
   - Microsoft Word 97 – **Y2KEFILE.DOC**; or
   - Adobe Acrobat (requires Acrobat Reader 3.x or higher) – **Y2KEFILE.PDF**; or
   - HTML/Text – **Y2KEFILE.HTML**

5. Complete the E-File reporting template – **Y2KEFILE.XLS**.
   - Report all medical devices and/or scientific research equipment that are Y2K compliant.

6. Use one of the following methods to return the completed E-File:
   - **EMail** to y2kstatus@bah.com, or
   - **3.5" diskette or CD-ROM** mailed to:
     Year 2000 Coordinator (HFZ-Y2K)
     Center for Devices and Radiological Health, FDA
     9200 Corporate Boulevard
     Rockville, Maryland 20850
     USA

Helpful Tips

✓ Complete a separate submission packet for each Division that manufacturers medical devices and/or scientific research equipment.

✓ For the FDA Classification Number (Lines 5a and 5b on **Compliant Products – FORM FDA 3474**) use the device classification as identified in the Device Classification Regulation of 21 CFR 860-892.
   - For details and instructions see the enclosed **List of Product Classification Names**.
   - For a product that has not been classified by the FDA or is scientific research equipment, please provide a generic description (e.g., mass spectrometer).

✓ To use E-File you must use **Microsoft Excel 97** or **Microsoft Excel 5.0/95**.

✓ The **Column Width**, for an E-File submission, indicates the maximum number of characters allowed in that field.

✓ For an E-File submission the following columns must contain data:

Column	Column Name
A	Man-name
D	Class-name
E	Prod-name
F	Model-nbr
J	FirstName
K	LastName
L	Address1
R	Telephone
U	SubType

✓ Each row for an E-File submission, should have the appropriate manufacturer, product, or Y2K contact person information entered in its respective column.
   - For details see the enclosed **E-File Reporting Format Instructions**.

✓ If you have any questions about completing the forms or about the Federal Y2K Biomedical Equipment Clearinghouse please call toll free 1-877-744-1522 between 8:30am and 5:00pm Monday through Friday Eastern Time, or EMail the Y2K Clearinghouse at y2kstatus@bah.com.